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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,295	06/29/2001	William J. Boyle	ACS-56001 (26361)	1994

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FULWIDER PATTON LEE & UTECHT, LLP
HOWARD HUGHES CENTER
6060 CENTER DRIVE
TENTH FLOOR
LOS ANGELES, CA 90045

EXAMINER

RAGONESE, ANDREA M

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/897,295

Applicant(s)

BOYLE ET AL.

Examiner

Andrea M. Ragonese

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-32 and 41-51 is/are pending in the application.
- 4a) Of the above claim(s) 14-19 and 27-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-13, 20-26 and 41-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The amendment filed on December 2, 2004 has been entered. Examiner acknowledges that **claims 3, 10, 20 and 21** have been amended, **claims 1-2** have been canceled and **claims 41-51** have been added. Subsequently, **claims 3-13, 20-26 and 41-51** under consideration, while **claims 14-19 and 27-32** have been withdrawn from further consideration.

Response to Arguments

2. Applicant's arguments, see pages 9-10, filed December 2, 2004, with respect to the rejection of **claims 3-13 and 21-26** under 35 U.S.C. § 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, new grounds of rejection are made hereinafter.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. **Claims 43 and 51** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, **claim 43** recites a "reinforcing member" that "is embedded in the wall which forms the expandable housing" and **claim**

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51 recites a "reinforcing member" that "helps to bias the expandable housing in the contracted position." Both of these claim limitations were not present in the original disclosure and therefore, are considered new matter, which cannot be entered in an amendment.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. **Claims 3-13, 20-26 and 41-51** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hopkins et al. (US 6,544,279) in view of Amplatz (US 6,123,715).

Regarding **claims 3 and 41**, Hopkins et al. discloses a restraining device for maintaining a self-expanding medical device on a delivery device, including an expandable housing portion (594) that is made primarily from an elastic material, which

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is stretchable between the contracted position and expanded position. However, Hopkins et al. do not explicitly recite at least one reinforcing member associated therewith for providing additional column strength to the housing portion. On the other hand, it would be obvious to one with ordinary skill in the art to incorporate reinforcing members. For example, Amplatz teaches the use of reinforcing members for providing additional strength to a guiding catheter (column 3, lines 40-49). Thus, it would be within the scope of the invention and obvious to one with ordinary skill in the art to incorporate reinforcement members in the expandable housing of Hopkins et al. for the purpose of controlling the expansion/rigidity. It is known to combine different materials to achieve different strengths and expansion ability.

Regarding **claims 4 and 42**, Hopkins et al. as modified discloses that as applied to **claims 3 and 41**, as well as a plurality of reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion is within the scope of this modification and would be obvious to one with ordinary skill in the art.

Regarding **claim 5**, Hopkins et al. as modified discloses that as applied to **claim 4**, as well as reinforcing members that extend substantially along the length of the expandable housing portion but do not interfere with the expansion of the elastic material is within the scope of this modification and would be obvious to one with ordinary skill in the art.

Regarding **claims 6 and 44**, Hopkins et al. as modified discloses that as applied to **claims 5 and 41** as well as reinforcing members (braids) that are elongated bar-like members made from a material having high stiffness (column 4, lines 11-24).

Regarding **claims 7 and 45**, Hopkins et al. as modified discloses that as applied to **claims 3 and 41** as well as an elastic material that is selected from a group of materials, which includes silicone, polyurethane, polyisoprene and lower durometer PEBAX.

Regarding **claims 8 and 46**, Hopkins et al. as modified discloses that as applied to **claims 4 and 41** as well as Amplatz further teaches a reinforcing member that is made from a material selected from a group including stainless steel, polymeric material, and Nitinol.

Regarding **claims 9 and 47**, Hopkins et al. as modified discloses that as applied to **claims 8 and 41** as well as radiopacity material (598). It would be further within the scope of the modification to have the reinforcing members loaded with a material having high radiopacity.

Regarding **claims 10 and 48**, Hopkins et al. as modified discloses that as applied to **claims 3 and 41** as well as an expandable housing portion that is made from a substantially tubular-shaped material that is highly elastic. However, Hopkins et al. do not explicitly recite a plurality of reinforcing members disposed within the tubular elastic material to provide additional column strength to the housing portion. On the other hand, it would be obvious to one with ordinary skill in the art to incorporate reinforcing members. For example, Amplatz teaches the use of reinforcing members for providing

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additional strength to a guiding catheter (column 3, lines 40-49). Thus, it would be within the scope of the invention and obvious to one with ordinary skill in the art to incorporate reinforcement members in the expandable housing of Hopkins et al. for the purpose of controlling the expansion/rigidity. It is known to combine different materials to achieve different strengths and expansion ability.

Regarding **claims 11-13, 43 and 48-50**, Hopkins et al. as modified discloses that as applied to **claims 4 and 41**. However, the following claims disclose location options for the reinforcing members. Since no particular location has been deemed critical, they can be considered equivalents. Thus, it would be within the scope of the modification to have the reinforcing members disposed within the elastic material forming the expandable housing portion, attached to the surface of the expandable housing portion, and/or disposed along the expandable housing portion.

Regarding **claim 20**, Hopkins et al. as modified discloses that as applied to **claim 3**, as well as an expandable housing portion (594) that includes a low expansion section with at least one expansion member (such as 590) disposed within the low expansion section to provide the elasticity needed to move the housing portion between the contracted position and expanded position. "Low expansion section" is considered a relative phrase and a basis for comparison has not been provided.

Regarding **claim 21**, Hopkins et al. as modified discloses that as applied to **claim 3**. However, Hopkins et al. do not explicitly recite a plurality of low expansion sections and a plurality of expansion members disposed between low expansion sections. On the other hand, it would be obvious to one with ordinary skill in the art to incorporate

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reinforcing members. For example, Amplatz teaches the use of reinforcing members for providing additional strength to a guiding catheter (column 3, lines 40-49). Thus, it would be within the scope of the invention and obvious to one with ordinary skill in the art to incorporate reinforcement members in the expandable housing of Hopkins et al. for the purpose of controlling the expansion/rigidity. It is known to combine different materials to achieve different strengths and expansion ability. Further, to have the expansion members disposed between the low expansion sections would further be obvious to one with ordinary skill in the art.

Regarding **claim 22**, Hopkins et al. as modified discloses that as applied to **claim 21** as well as radiopacity material (598). It would be further within the scope of the modification to have the reinforcing members loaded with a material having high radiopacity.

Regarding **claim 23**, Hopkins et al. as modified discloses that as applied to **claim 21** as well as an elastic material that is selected from a group of materials, which includes silicone, polyurethane, polyisoprene and lower durometer PEBAX.

Regarding **claim 24**, Hopkins et al. as modified discloses that as applied to **claim 23** as well as low expansion sections that are made from a material selected from a group including cross-linked HDPE, polyolefin and polyamide.

Regarding **claim 25**, Hopkins et al. as modified discloses that as applied to **claim 21**. Further, this modification would yield expansion members that extend longitudinally along the length of the expandable housing portion.

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Regarding **claim 26**, Hopkins et al. as modified discloses that as applied to **claim 25**. Further, this modification would yield expansion members that include means for preventing the low expansion sections from tearing as the expandable housing portion expands from the contracted position to the expanded position.

Regarding **claim 51**, Hopkins et al. as modified discloses that as applied to **claim 41** as well as teaching reinforcing members that are fully capable of helping to bias the expandable housing portion in the contracted position.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese whose telephone number is 571-272-4804**. The examiner can normally be reached on Monday through Friday from 9:00 am until 5:00 pm.

9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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AMR

February 22, 2005



Henry Bennett
Supervisory Patent Examiner
Group 3700